No. 1:17-md-02775

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO
BHR TRACK Cases Identified in Exhibit A

DEFENDANT SMITH & NEPHEW, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AS TO ALL CLAIMS OF PLAINTIFFS WITH IMPLANT DATES PRIOR TO OCTOBER 2009

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INTRODUCTION AND SUMMARY

Defendant Smith & Nephew, Inc. ("Smith & Nephew") respectfully submits this memorandum in support of its Motion for Summary Judgment as to All Claims of Plaintiffs in the BHR Track with Implant Dates Prior to October 2009.[1] Through the multi-year course of general liability discovery in this MDL, Plaintiffs have failed to adduce evidence to support the essential elements of their claims relating to BHR implants before October 2009.[2] Without such evidence, these claims cannot proceed, regardless of any individual-case facts, and thus summary judgment is appropriate at this time.

In this MDL, Plaintiffs' core "theory of the case" turns on foreign "ad hoc" registry data, which they have argued "showed significantly worse success rates for the BHR in [1] women and [2] patients with smaller head sizes." *Redick* Memorandum (May 17, 2021) [D.E. 2715] ("*Redick* Mem.") at 2; *Mosca* Memorandum (July 19, 2021) [D.E. 2905] ("*Mosca* Mem.") at 2-3. But, as this Court explained in its *Sedgwick* summary judgment decision, "Smith & Nephew did not begin to receive ad hoc reports from Australian and UK registries showing longer-term higher rates of revision for patients with smaller head sizes until 2009." *See* Memorandum (Aug. 19, 2021) [D.E. 2977] ("*Sedgwick* Mem.") at 18; *Mosca* Mem. at 7-8 (discussing ad hoc reports from October 2009). "Dear Doctor" letters or other alleged statements made ***before*** the receipt of these ad hoc reports cannot support liability for plaintiffs implanted with the BHR prior to October 2009.

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[1] Exhibit A identifies 307 Plaintiffs in this MDL as of December 17, 2021, with BHR implants prior to October 2009, including the date of implant(s) as reflected in their Short Form Complaints and/or medical records. Certain plaintiffs allege bilateral BHR implants, and if one is prior to October 2009 and one after, this Motion applies only to the implant prior to October 2009.

[2] In so stating, Smith & Nephew does not concede that Plaintiffs *have* adduced evidence to support essential elements of their claims regarding October 2009 and later implants. However, for purposes of this Motion, Smith & Nephew has adopted a conservative date. Smith & Nephew reserves all rights with respect to future motions for summary judgment affecting implants in other date ranges and/or as to individual plaintiffs or groups of plaintiffs on this or any other grounds.

Plaintiffs contend that Smith & Nephew "failed to warn the FDA" by not reporting these registry data, and that Smith & Nephew's representations to doctors of the device's overall success rates were rendered misleading by the omission of these ad hoc data for these subpopulations. These claims are unsupported for Plaintiffs implanted with the BHR prior to October 2009. As this Court ruled in *Sedgwick*, Smith & Nephew did not begin receiving ad hoc reports from the Australian registry until 2009, and Plaintiffs have "identified no information that . . . Smith & Nephew should have disclosed to the FDA" prior to that time. *Sedgwick* Mem. at 13-14. Indeed, even for later implant dates, the Court ruled in *Redick* and *Mosca* that Plaintiffs failed to support their claim of failure to warn the FDA on "the difficult element of causation" because the record does not support "a jury's inference that the ad hoc data at issue here would have been published in the MAUDE database." *Redick* Mem. at 16-17; *Mosca* Mem. at 16. This failure is even more glaring for Plaintiffs with implant dates prior to October 2009, *i.e.*, before Smith & Nephew had the data Plaintiffs assert it should have reported to FDA.

Likewise, Plaintiffs' claims for misrepresentation and breach of warranty arising from implants before October 2009 fail because "there is no evidence Smith & Nephew had additional information that contradicted . . . assertions" it made to doctors before their procedures. *Sedgwick* Mem. at 18. Again, while Plaintiffs contend Smith & Nephew should have altered its communication of revision rates because of the ad hoc data, Smith & Nephew did not have this information before these Plaintiffs' implant procedures, and Plaintiffs have identified no express warranties made to them that were breached.

In light of the Court's rulings and the opinions of their own experts, Plaintiffs cannot carry their burden of proving the essential elements of their claims against Smith & Nephew in cases involving Plaintiffs who underwent the BHR procedure prior to October 2009. Smith & Nephew

submits that the time is appropriate for the Court to address this legal challenge, because it would serve the goals underlying the MDL by resolving a significant number of cases, thus avoiding the unnecessary waste of resources and the risk of conflicting rulings on remand as to common issues that cut across multiple similar cases in this MDL.

Summary judgment should be granted to Smith & Nephew as to these cases.

BACKGROUND

A. Federal Law Governing Medical Devices.

In 1976, Congress passed the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA"). The MDA imposed a regime of detailed federal oversight to govern medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008); *Walker v. Medtronic, Inc.*, 670 F.3d 569, 572 (4th Cir. 2012). To alleviate the "undu[e] burden[]" of differing state regulation, Congress adopted a "general prohibition on non-Federal regulation" of medical devices by incorporating an express-preemption clause into the MDA. H.R. Rep. No. 94-853, at 45 (1976); *Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001) (en banc) ("need for national uniformity in product regulation" was "one of the explicit goals of the MDA"). Accordingly, no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a). Additionally, because the MDA provides that all actions to enforce FDA requirements "shall be by and in the name of the United States," 21 U.S.C. § 337(a), suits by private parties "for noncompliance with the medical device provisions" are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

The MDA establishes three classes of medical devices, organized according to the level of federal oversight needed to ensure their safety. *Id.* The BHR falls within Class III, the category of devices that are useful in "supporting or sustaining human life," or that otherwise "present[] a

potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C). Class III medical devices are subject to a "rigorous" level of federal regulation. *Riegel*, 552 U.S. at 317-18. As this Court has explained, Class III medical devices such as the BHR "must receive FDA approval before they may be marketed." *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prods. Liab. Litig.*, 300 F. Supp. 3d 732, 737 (D. Md. 2018) ("*In re BHR*") (citing 21 U.S.C. § 360e(a)). In particular, "[t]he rigor of the premarket approval [PMA] process has been well-documented, requiring nearly 1,200 hours of review and substantial filings for each device." *Id*. After the device manufacturer submits to FDA "information regarding, among other things, the device's design, manufacture, and safety and effectiveness," "the FDA 'weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Id*. (quoting 21 U.S.C. § 360c(a)(2)(C)). Thus, "[a] manufacturer of an FDA approved device does not violate federal regulations by claiming its device is safe. That is exactly what FDA approval means." *Id*. at 745.

Upon receipt of a PMA, the manufacturer "is forbidden 'to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness' unless the manufacturer submits an additional application for FDA review." *Id*. (quoting *Riegel*, 552 U.S. at 319). PMA devices are also subject to certain post-approval reporting requirements, specifically to report "adverse events" concerning the device and submit annual reports. *In re BHR,* 300 F. Supp. 3d at 737 (citing 21 U.S.C. § 360i(a)(1)(A)). "The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." *Riegel*, 552 U.S. at 319-20 (citing U.S.C. § 360e(e)(1)); *see also In re BHR*, 300 F. Supp. 3d at 737 n.5 ("Only the FDA has the authority to withdraw approval

from a device.").

B. Regulatory History of the BHR Device.

FDA granted PMA to Smith & Nephew for the BHR in May 2006. *Id*. at 736. The FDA-approved BHR included femoral head sizes with diameters ranging from 38 mm to 58 mm, and the device was approved for use in both men and women. *See* SN_BHR_MDL_0031019 (Ex. B) at 3. The FDA-approved labeling specified that "[t]he BHR System is intended for patients who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty due to an increased possibility of requiring future ipsilateral [*i.e.*, same side] hip joint revision." *Id*. at 4.

Pursuant to its post-approval reporting requirements, Smith & Nephew submitted annual reports to FDA beginning in 2006, and each year FDA sent a letter back to Smith & Nephew following the submission of its annual report verifying that Smith & Nephew had fully complied with its PMA reporting requirements.[3] In 2010, the BHR labeling was revised to include a warning that the risk of revision was higher for female patients and those receiving smaller BHR component sizes. SN_BHR_MDL_0032345 (Ex. Q) at 4 ("Based upon literature reports and the clinical study, the following were identified as risk factors for revision: Patients who are female; who receive a smaller component size . . . . The more risk factors a patient has, the greater the risk of procedure failure requiring a revision to the hip.").[4]

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[3] *See* SN_BHR_MDL_0024725; SN_BHR_MDL_0024735; SN_BHR_MDL_0445713; SN_BHR_MDL_2343691; SN_BHR_MDL_0019627; SN_BHR_MDL_0025483; SN_BHR_MDL_0025741; SN_BHR_MDL_2249476; SN_BHR_MDL_0026233; SN_BHR_MDL_0026614-15; SN_BHR_MDL_0027007; SN_BHR_MDL_3103365-66; SN_BHR_MDL_3103340; SN_BHR_MDL_2424867 (Exs. C through P).

[4] In 2015, Smith & Nephew voluntarily withdrew smaller BHR component sizes (46 mm and smaller femoral head sizes), and contraindicated the device for female patients. *In re BHR*, 300 F. Supp. 3d at 736; SN_BHR_MDL_1470770 (Ex. R) at 3 (BHR sizing chart, limited to BHR femoral head sizes with diameters of 48 mm to 58 mm); *id*. at 4 ("Contraindications" include "[p]atients

C. The Judicial Panel on Multi-District Litigation's Creation of This MDL.

On April 5, 2017, the Judicial Panel on Multidistrict Litigation centralized proceedings before this Court for actions involving "the design, manufacture, marketing or performance of Smith & Nephew's BHR system." *In re Smith & Nephew BHR & R3 Hip Implant Prods. Liab. Litig.*, 249 F. Supp. 3d 1348, 1350 (J.P.M.L. 2017). The JPML concluded "that centralization in the District of Maryland will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation." *Id.* The JPML explained that consolidation in the District of Maryland was appropriate because this Court is "an experienced MDL judge with the willingness and ability to manage this litigation efficiently," and is "well situated to structure this litigation so as to minimize delay and avoid unnecessary duplication of discovery and motion practice." *Id.* at 1352.

D. Plaintiffs' Claims and Theories of Liability.

In the Master Amended Consolidated Complaint for the BHR-Track cases (Aug. 11, 2017) [D.E. 124] ("MACC"), Plaintiffs alleged that Smith & Nephew was liable under "eight state common law theories of liability—strict products liability; negligence; strict liability for failure to warn; negligent failure to warn; negligent misrepresentation; negligence per se; breach of express warranty; and manufacturing defect." *In re BHR*, 300 F. Supp. 3d at 735.

Applying the preemption provisions of the FDCA and the pleading requirements of Rule 8, the Court held that Plaintiffs cannot state a claim for strict liability under a products liability or failure to warn theory, because prevailing on those claims "would require finding [the BHR]

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who are female"). The BHR continues to remain FDA-approved, and the larger component sizes remain on the market for use in male patients. *E.g.,* Deposition of Jeffrey Shapiro, M.D. (*Albritton*) (Mar. 23, 2021) (Ex. S) at 211 ("Q. Do you know that the [50]-millimeter size BHR heads are still on the market? A. I know it is.").

unreasonably dangerous." *Id.* at 743. The Court also dismissed Plaintiffs' claim for manufacturing defect as inadequately pled. *Id.* at 750.

As to Plaintiffs' remaining claims and theories—negligent failure to warn, negligent misrepresentation, negligent training, negligence *per se*, and punitive damages—the Court ruled that the claims "at least facially" fit within the narrow exception for parallel state claims, *id.* at 743, but narrowed the scope of the claims under the applicable preemption doctrines. In particular:

- "Any claim . . . that Smith & Nephew had a duty to change its labeling or communicate information to patients or the medical community, or any other duty not also imposed by the FDA, should be preempted as an attempt to impose requirements that add to or differ from federal regulations." *Id.* at 745.
- "Any claim that Smith & Nephew had a duty to warn the general public or the medical community is . . . expressly preempted because there is no such parallel federal requirement." *Id.*
- Plaintiffs' claims "cannot be supported by representations that the FDA required Smith & Nephew to make because liability would then rely . . . on Smith & Nephew complying with federal regulations." *Id.*
- "[A]ny other cause of action that might require proof that the BHR device was unreasonably dangerous" is preempted. *Id.* at 743 n.9.
- "To the extent the plaintiffs adopt, or their underlying state failure to warn claims require, a fraud-on-the-FDA claim, that claim would be preempted." *Id.* at 747 n.15.

In its *Daubert* Ruling, the Court reiterated its prior holdings that Plaintiffs may not introduce argument or evidence regarding preempted claims that: (i) challenge the FDA's determination that the BHR is safe and effective, *see* Memorandum (Mar. 1, 2021) [D.E. 2501] ("*Daubert* Ruling") at 7–10, 15–18; (ii) contend the BHR's warnings, including the warnings contained in the labeling or instructions for use ("IFU"), were inadequate, *id.* at 10–15; (iii) contend Smith & Nephew "did not notify surgeons already using its implants about failure issues when S&N made changes to the IFUs," that the BHR had a "1,000 surgery learning curve,"

or about "appropriate patient selection," *id.* at 13; or (iv) "suggest Smith & Nephew had a duty to withdraw its BHR system from the market earlier," *id.* at 15.

The Court further held that Plaintiffs cannot "challenge the premarket approval process" itself by claiming Smith & Nephew "was negligent in omitting material facts when submitting its PMA." *Id*. at 9. "FDA has the power to require the submission of any additional information it deems necessary during the approval process, so a state law negligence claim which would impose further disclosure requirements than already provided for in the statute is preempted." *Id*. Rather, Plaintiffs' claims must be based on evidence that "Smith & Nephew failed to make adequate disclosures . . . *after* receiving premarket approval." *Id*. at 10.

For the remaining claims, Plaintiffs' core "theory of the case" is predicated on foreign registry data, which they have argued "showed significantly worse success rates for the BHR in [1] women and [2] patients with smaller head sizes." *Redick* Mem. at 2.[5] The Master Amended Consolidated Complaint, for example, alleges that international registry data suggested an increased revision rate in patients "with a femoral head size of less than 50 mm," MACC ¶¶ 99, 121, and that Smith & Nephew "concealed the true failure rate of the BHR for women and patients receiving smaller head sizes," *id.* ¶ 77. Plaintiffs' experts have likewise opined that Smith & Nephew's marketing for the BHR should have "differentiat[ed] among subpopulations like women

[5] *See also Redick* Mem. at 2 (Negligent Misrepresentation) (highlighting plaintiffs' argument that registry data "showed significantly worse success rates for the BHR in women and patients with smaller head sizes"); *id.* at 19 ("The plaintiffs contend that extra-labeling statements and marketing materials . . . misrepresented the actual revision risk to female patients and patients needing smaller head sizes"); *id.* at 34 (Breach of Express Warranty) ("For the reasons stated above in the court's discussion of the plaintiff's negligent misrepresentation claim, whether Smith & Nephew's representations as to the risks of revision for female patients and patients needing smaller head sizes were inaccurate or misleading is a question for the jury").

and smaller head sizes." General Causation Expert Report of Jeffrey F. Shapiro, M.D. (July 15, 2020) ("Shapiro (MDL) Report") (Ex. T) at 23, 25.

In particular, Plaintiffs point to "ad hoc" reports from the Australian registry that Smith & Nephew received beginning in October 2009, which Plaintiffs contend should have been reported to FDA and reflected in Smith & Nephew's "Dear Doctor" letters. *Id.* at 23 ("In 2009, Smith & Nephew learned of higher-than-expected failure rates for women and patients with smaller head sizes through reports from the Australian registry."); *see also* Larry Spears Expert Report (July 15, 2020) (Ex. U) ("Spears Report") at 21 ("Smith & Nephew had data as far back as 2009 from Registry Ad-Hoc reports showing higher failure rates in female patients"); Engineer's Report of Mari Truman (July 15, 2020) ("Truman (MDL) Report") (Ex. V) at 31.[6]

The Australian registry generates these "ad hoc" reports "when an organization . . . approach[es] the registry for information and analysis to be undertaken to answer specific questions." Deposition of Stephen Graves (Nov. 30, 2021) ("Graves Dep.") (Ex. Y) at 32. Pursuant to the registry's policies, data from the ad hoc reports "may only be used for internal or regulatory affairs purposes," and "must not be used in publications, promotional, or marketing material." *Id.* at 43. Plaintiffs' experts contend that Smith & Nephew "fail[ed] to provide full disclosures in the Dear Doctor letters it sent," because the letters did not reflect the higher rates of revision from the ad hoc registry data for women and patients with small heads. Expert Report of Dr. Yadin B. David (July 11, 2020) ("David (MDL) Report") (Ex. Z) at 37; *see, e.g.*, *Redick* Mem. at 20, 32-34 (describing Plaintiffs' negligence claim).[7]

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[6] Ad Hoc Report 408 is dated September 25, 2009, reflecting the date the report was requested; Smith & Nephew received the report on October 16, 2009. SN_BHR_MDL_0777009 (Ex. W). Ad Hoc Report 425 was received on October 19, 2009. SN_BHR_MDL_3026697 (Ex. X).

[7] Plaintiffs' experts are not critical of the BHR in males with femoral head sizes of 50 mm and larger. *See* Defendant Smith & Nephew, Inc.'s Mem. in Support of Its Motion for Summary

The Court has also ruled on several summary judgment motions. Among others, the Court granted summary judgment to Smith & Nephew in *Sedgwick*, where the plaintiff had the BHR device implanted in September 2007. *Sedgwick* Mem. at 4. The Court held that, in order to prevail on the failure-to-warn claim, a plaintiff "must show that if Smith & Nephew had 'properly reported the adverse events to the FDA as required under federal law, that information would have reached [his] doctors in time to prevent [his] injuries.'" *Id*. at 13. Mr. Sedgwick's claim failed as a matter of law because he "identified no information that he claims Smith & Nephew should have disclosed to the FDA that, if publicized, would have reached [his doctor] in time to alter his decision to have the BHR implanted." *Id*. at 13-14. Rather, Plaintiffs' "arguments were predicated on the failure to disclose to the FDA ad hoc data and reports that Smith & Nephew received *after* Sedgwick's surgery." *Id.* at 14.

The Court likewise held that Mr. Sedgwick's negligent misrepresentation claims failed as a matter of law because the alleged misrepresentations "were either (1) consistent with the FDA label at the time of Mr. Sedgwick's surgery, and thus the court's preemption ruling shields them from liability regarding those statements, or (2) not false or misleading because Smith & Nephew knew them to be true or believed them to be true at the time of Mr. Sedgwick's surgery." *Id*. at 17. In particular, "[r]epresentations that the five-year revision rate of the BHR was one to three

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Judgment, Relating to All Male Plaintiffs Implanted with BHR Devices with Large Femoral Head Sizes, (May 26, 2021) [D.E. 2762-1] ("Male Large Head Mot. for Summ. J."); Deposition of Larry Spears (Sept. 9, 2020) ("Spears Dep. II") (Ex. AA) at 81-82 (expert has "not offer[ed] an expert opinion that the BHR was misbranded for men or for patients with head sizes 48-millimeters and above."); Deposition of Dr. Yadin David (Sept. 22, 2020) ("David Dep.") (Ex. BB) at 227 (expert does not have "any complaints about the BHR with respect to men and head sizes of 48 and above."); Deposition of Jeffrey Shapiro, M.D. (MDL) (Sept. 11, 2020) ("Shapiro (MDL) Dep.") (Ex. CC) at 208–11 (males with larger head sizes are "doing well, *if not better than* the traditional metal on poly," and "the bigger heads do not appear to have the same problems as the smaller heads.").

percent overall were consistent with information contained within the BHR's FDA label at the time of Mr. Sedgwick's surgery" and "there is no evidence that this representation did not reflect Smith & Nephew's knowledge of the BHR's overall revision rates up until the point of the surgery." *Id*. The Court rejected Plaintiff's attempt to rely on "information predat[ing] the FDA's PMA approval of the device" as a "preempted attempt to undermine the FDA's PMA approval process and the FDA-approved BHR label." *Id*. at 18. And Plaintiff could not rely on the ad hoc registry data, because "Smith & Nephew did not begin to receive ad hoc reports from Australian and UK registries showing longer-term higher rates of revision for patients with smaller head sizes until 2009." *Id*. Plaintiff's claims therefore could not proceed, and the Court granted summary judgment to Smith & Nephew.

GOVERNING LAW[8]

Federal Rule of Civil Procedure 56 provides that summary judgment should be granted on a "claim" or "part of [a] claim" "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A party asserting that a fact cannot be genuinely disputed must support the assertion by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A). In turn, "[a] party opposing a properly supported motion for summary judgment 'may not rest upon the mere allegations or denials of [his] pleadings,' but rather must 'set forth specific facts showing that there is a genuine issue for trial.'" *Brown v. Neuberger, Quinn, Gielen, Rubin & Gibber*, *P.A.*, 731 F. Supp. 2d 443, 449 (D. Md. 2010) (quoting

[8] Smith & Nephew's motion does not depend upon which underlying State law applies to the Complaints at issue, which involve BHR hip implant patients who had the procedure prior to October 2009. *Cf. In re BHR*, 300 F. Supp. 3d at 740 (addressing legal issues without the "need to analyze the elements of underlying state laws.").

Bouchat v. Baltimore Ravens Football Club, Inc., 346 F.3d 514, 522 (4th Cir. 2003)), *aff'd*, 495 F. App'x 350 (4th Cir. 2012). For example, "causation is a required element in every product[s] liability case," and summary judgment can therefore be granted where causation evidence is lacking. *In re Bausch & Lomb Inc. Contacts Lens Sol. Prods. Liab. Litig.*, 693 F. Supp. 2d 515, 520 (D.S.C. 2010), *aff'd sub nom. Fernandez-Pineiro v. Bausch & Lomb, Inc.*, 429 F. App'x 249, 252-53 (4th Cir. 2011) (per curiam).

Courts "view the facts and draw reasonable inferences in the light most favorable to the party opposing the [summary judgment] motion," *Scott v. Harris*, 550 U.S. 372, 378 (2007) (internal quotation marks and citation omitted), but "only if there is a 'genuine' dispute as to those facts." *Intel Corp. Inv. Pol'y Comm. v. Sulyma*, 140 S. Ct. 768, 779 (2020) (citation omitted). The court "must abide by the 'affirmative obligation of the trial judge to prevent factually unsupported claims and defenses from proceeding to trial.'" *Brown*, 731 F. Supp. 2d at 449 (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993)). Summary judgment may be granted where a party's expert has admitted facts that render disputes as to other factual questions immaterial. *See, e.g., Equal Rights Ctr. v. Equity Residential*, No. CCB-06-1060, 2016 WL 1258418, at *13 (D. Md. Mar. 31, 2016); *Baltimore Aircoil Co. v. SPX Cooling Techs., Inc.*, No. CCB-13-2053, 2016 WL 4426681, at *4 (D. Md. Aug. 22, 2016), *aff'd*, 721 F. App'x 983 (Fed. Cir. 2018).

ARGUMENT

I. SUMMARY JUDGMENT SHOULD BE GRANTED TO SMITH & NEPHEW ON PLAINTIFFS' FAILURE TO WARN THE FDA CLAIMS.

A. Plaintiffs Cannot Support a Failure to Warn Claim with Allegations That Smith & Nephew Failed to Report Adverse Events to the FDA.

Summary judgment should be granted to Smith & Nephew on Plaintiffs' negligent failure to warn claims. This Court already has dismissed Plaintiffs' claims that Smith & Nephew failed to warn the medical community or the public. With regard to Plaintiffs' claims that Smith &

Nephew failed to warn the FDA, Plaintiffs cannot identify any failure to provide information to the FDA relating to Plaintiffs with procedures prior to October 2009, that was the proximate cause of their injuries. Causation is a required element of a negligent failure to warn claim. *See, e.g.*, *Block v. Abbott Labs.*, No. 99 C 7457, 2002 WL 485364, at *4 (N.D. Ill. Mar. 29, 2002) ("While failure-to-warn law may vary from state to state, all states which recognize such a claim require, at a minimum, proof of causation and damages."); *accord* James A. Henderson, Jr. & Aaron D. Twerski, *Products Liability, Problems and Process* 387–88 (1987) ("Under every approach taken in every jurisdiction, the plaintiff must show that the defendant's failure to warn was the proximate cause of the plaintiff's injury.").

As previously explained in Smith & Nephew's memorandum in support of its motion for summary judgment regarding large femoral heads, the Court is authorized to grant summary judgment across multiple cases consolidated in this MDL proceeding. *See* Male Large Head Mot. for Summ. J. at 15-16; *e.g.*, *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig. (No. II) MDL 2502*, 892 F.3d 624 (4th Cir. 2018) ("*In re Lipitor*") (affirming district court's grant of summary judgment for defendant against thousands of products liability plaintiffs in an MDL where plaintiffs lacked evidence of causation); *In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* (*No. II*) ("*In re Mirena*"), 387 F. Supp. 3d 323, 358 (S.D.N.Y. 2019) (granting summary judgment against "approximately 920 plaintiffs in this MDL"), *aff'd* 982 F.3d 113, 121 (2d Cir. 2020). The Fourth Circuit has held that "[i]t is well established that a transferee court may dispose of cases in an MDL through summary judgment—and indeed, they often do," particularly where the motions involve "common" issues that the transferee court is best positioned to address. *In re Lipitor*, 892 F.3d at 648; *see also* Federal Judicial Center, Manual for Complex Litigation § 22.36 (4th ed. 2004) ("An MDL transferee judge

has authority to dispose of cases on the merits—for example, by ruling on motions for summary judgment."). Where a party fails to introduce sufficient evidence regarding a common issue such as "general causation," summary judgment is appropriate, and courts will not "credit a nonmovant's merely speculative assertion that some evidence that they have not specifically identified could have created a genuine dispute." *In re Mirena*, 982 F.3d at 125.

These principles apply squarely to Plaintiffs' failure to warn claims for the cases in the BHR track of this MDL involving Plaintiffs who underwent the BHR procedure prior to October 2009. This Court previously ruled that "[a]ny claim that Smith & Nephew had a duty to warn the general public or the medical community is . . . expressly preempted because there is no such parallel federal requirement." *In re BHR*, 300 F. Supp. 3d at 745. Plaintiffs' claims based on a failure to warn Plaintiffs or their surgeons are therefore no longer in this case. This Court ruled, however, that federal law does not preempt any existing "state failure to warn claims that support holding Smith & Nephew liable for its alleged failure to report specific information to the FDA." *Id*. Accordingly, Plaintiffs' only remaining failure to warn theory is a claim based on alleged failure to warn the FDA. Applying the Court's recent rulings in *Redick* and *Sedgwick* granting summary judgment as to Plaintiffs' failure-to-warn-the-FDA claim, it is apparent that no failure to warn claim survives for any population, and especially for Plaintiffs who obtained the device prior to October 2009, because Plaintiffs have not identified information that Smith & Nephew failed to report to FDA that would have reached Plaintiffs' doctors in time to prevent their alleged injuries.

Courts that have allowed plaintiffs to proceed with a claim predicated on the failure to provide information to FDA have emphasized that these plaintiffs "face a causation hurdle that would not otherwise exist." *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring). As this Court explained in granting summary judgment to Smith &

Nephew on Plaintiff Paula Redick's failure-to-warn-the-FDA claim, "[i]n order to prevail on a non-preempted failure to warn claim, the plaintiffs must show that if Smith & Nephew had 'properly reported the adverse events to the FDA as required under federal law, that information would have reached her doctors in time to prevent her injuries.'" *Redick* Mem. at 16 (citing *Daubert* Ruling, at 14 n.3; *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1096–97 (N.D. Cal. 2016)); *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 776 (5th Cir. 2011)).

This Court has further held that "plaintiffs appropriately have disavowed any arguments concerning discretionary actions the FDA may or may not have taken had it received" different information following PMA. *Redick* Mem. at 16 (citing *Daubert* Ruling at 23). Plaintiffs conceded at the *Daubert* hearing, on behalf of all plaintiffs in the BHR track, that "[n]one of [plaintiffs'] claims rely on what FDA would or would not have done." Hr'g Tr. (Jan. 27, 2021) (Ex. DD) at 31 ("I want to make that clear."). Accordingly, the Court has recognized that "the plaintiffs, appropriately, do not plan to offer speculative testimony about what the FDA might or might not have done if presented with different or additional information." *Daubert* Ruling at 23; *See Hughes*, 631 F.3d at 776 n.12 (rejecting claim that "FDA would have taken some regulatory action" as "entirely speculative"). As explained further in the motion for summary judgment regarding large femoral head sizes, Plaintiffs took this position for good reason, because their experts do not and cannot opine on what FDA would have done. Male Large Head Mot. for Summ. J. [D.E. 2762-1] at 16-19; *see, e.g.* Deposition of Larry Spears (Sept. 8, 2020) ("Spears Dep. I") (Ex. EE) at 113-14 (expert cannot "offer with any certainty any other actions that FDA would have taken other than asking more questions.").

Moreover, the Court held in the *Daubert* Ruling that Plaintiffs cannot "challenge the FDA's decision to grant a PMA," and their claims must be based on evidence that "Smith & Nephew

failed to make adequate disclosures . . . *after* receiving premarket approval." *Daubert* Ruling at 7, 10. Under *Buckman*, Plaintiffs cannot claim Smith & Nephew "was negligent in omitting material facts when submitting its PMA," because "FDA has the power to require the submission of any additional information it deems necessary during the approval process, so a state law negligence claim which would impose further disclosure requirements than already provided for in the statute is preempted." *Daubert* Ruling at 9.

Under these rulings, Plaintiffs' remaining "theory of causation is limited to showing that information or data Smith & Nephew was required to provide to the FDA would necessarily have been made public, such that the higher revision rates would have been incorporated into materials [the physician] read prior to [the plaintiff's] surgery." *Sedgwick* Mem. 13. Plaintiffs lack evidence that could satisfy this "causation hurdle" for any plaintiff in the MDL, and this insufficiency is especially glaring for plaintiffs who obtained their devices prior to October 2009.

As this Court noted in *Sedgwick*, considering a September 2007 procedure, the plaintiff "identified no information that he claims Smith & Nephew should have disclosed to the FDA that, if publicized, would have reached [plaintiff's physician] in time to alter his decision to have the BHR implanted." *Id*. 13-14. Plaintiffs contend that "ad hoc registry" data showing higher revision rates for females and patients with smaller femoral head sizes should have been reported to FDA. *See* pp. 9-10*, supra*. But Smith & Nephew did not have any relevant ad hoc data before October 2009, and Plaintiffs' experts have identified no earlier post-PMA data that they contend "the company failed to provide to FDA in violation of an FDA requirement." Spears Dep. I (Ex. EE) at 142-43 (Q: "[H]ave you identified anything else outside of this document from the 2007 to 2008 time period that the company failed to provide to FDA in violation of an FDA requirement?" A: "The answer to that is no"); *id*. at 139 (agreeing that "the 2007 and 2008" data "wouldn't be

something they'd have to do [report to FDA] under PMA Condition No. 4 or – or otherwise" under FDA regulations); Truman (MDL) Report (Ex. V) at 31 (contending 2009 registry data "should have been provided to the FDA"); *id*. at 57 (showing no "sub-population rate" registry data prior to 2009).

Indeed, even for later implants, this Court has rejected Plaintiffs' failure-to-warn-FDA claim for lack of causation, ruling that Plaintiffs cannot establish that "ad hoc data provided to the FDA would necessarily have been made public." *Redick* Mem. 16. The claim is plainly insufficient for Plaintiffs who obtained the device prior to October 2009, when Smith & Nephew did not even have the information it allegedly should have reported. Because Plaintiffs cannot show (i) any failure to warn the FDA for patients with implants prior to October 2009 or (ii) that any purported failure caused their injuries, summary judgment should be granted to Smith & Nephew on Plaintiffs' failure to warn claims for these cases.

B. Plaintiffs Cannot Support a Negligence *Per Se* Claim with Allegations That Smith & Nephew Failed to Report Adverse Events to the FDA.

For the same reasons, Plaintiffs' negligence *per se* claims fails. "The plaintiffs contend that a failure to report adverse events to the FDA, in violation of the PMA, constitutes negligence per se." *Redick* Mem. at 27. As with negligent failure to warn, causation is an essential element of a negligence *per se* claim. *See, e.g.*, 65 C.J.S. Negligence § 242 ("Establishing the existence of negligence *per se* settles only the questions of duty and breach, and a plaintiff still must prove causation before the plaintiff may recover."); 1 David G. Owen & Mary J. Davis, *Owen & Davis on Products Liability* § 2:19 (4th ed. May 2021 Update) ("[A] court will not apply a statutory standard if the violation was not a cause in fact, or not a proximate cause, of the plaintiff's harm.") As set forth above, however, Plaintiffs cannot establish that any purported failure by Smith & Nephew to report adverse events to the FDA caused their injuries, or even occurred before their

procedures. *Supra* § I.A. Indeed, "plaintiffs, appropriately, do not plan to offer speculative testimony about what the FDA might or might not have done if presented with different or additional information," *Daubert* Ruling at 23, and Plaintiffs cannot establish that "ad hoc data provided to the FDA would necessarily have been made public." *Redick* Mem. at 16. Thus, as the Court explained in granting summary judgment to Smith & Nephew on this claim in *Redick*, this "claim suffers from the same causal deficiencies as the plaintiffs' failure to warn claim, discussed above." There are no material facts to support a jury finding that had Smith & Nephew disclosed ad hoc data and reports from international registries to the FDA, the data would have been publicized such that it would have informed" Plaintiffs' implanting surgeons' "risk assessment of the BHR implant." *Id*. at 27-28.

Again, the claim is even more clearly deficient for plaintiffs who obtained their devices prior to October 2009, because Smith & Nephew did not even have the ad hoc registry data by that time. *See* pp. 9-10*, supra*. Plaintiffs cannot support their negligence per se claims for plaintiffs receiving BHR devices prior to October 2009, based upon a purported failure to report adverse events to the FDA, and summary judgment should be granted to Smith & Nephew.

II. SUMMARY JUDGMENT SHOULD BE GRANTED TO SMITH & NEPHEW ON PLAINTIFFS' NEGLIGENT MISREPRESENTATION AND BREACH OF EXPRESS WARRANTY CLAIMS.

A. Plaintiffs' Negligent Misrepresentation and Breach of Express Warranty Claims Fail.

To recover on their claims of negligent misrepresentation and breach of express warranty, Plaintiffs must show that Smith & Nephew made a material misrepresentation of fact that was the proximate cause of their alleged injuries. MACC ¶¶ 457-89 (Count V) (Negligent Misrepresentation); *id.* ¶¶ 500-66 (Count VII) (Breach of Express Warranties); *see, e.g.*, Owens & Davis, *supra*, § 3:11 (negligent misrepresentation); 2 William D. Hawkland et al., Hawkland UCC

Series § 2-313:5 (Dec. 2021 update) ("The plaintiff typically has the burden of proof on the issues that are elements of its case in chief, including … that breach of the express warranty caused damage."); *see*, *e.g.*, *Rock v. Oster Corp.*, 810 F. Supp. 665, 667 (D. Md. 1991) (granting summary judgment on breach of warranty claim where the alleged warranty was "immaterial" to alleged harm), *aff'd*, 983 F.2d 1057 (4th Cir. 1993). With regard to negligent misrepresentation, Plaintiffs allege that Smith & Nephew made representations that "were false, misleading, omitted material information or otherwise left a false impression about the safety of the BHR." MACC ¶ 458. With regard to breach of express warranty, Plaintiffs allege that Smith & Nephew expressly warranted that the BHR "was safe and effective for use when it was not." *See*, *e.g.*, *id.* ¶ 513; *see also id.* ¶¶ 514-63 (same).

First, as a matter of law, Plaintiffs cannot support claims based on the theory that Smith & Nephew warranted that the BHR is "safe and effective for use when it is not." *Id.* ¶ 513. This Court has dismissed as preempted any claim that (i) "might require proof that the BHR device was unreasonably dangerous" or (ii) challenges assertions by Smith & Nephew that the BHR was "safe." *In re BHR*, 300 F. Supp. 3d at 743 & n.9, 745; *see also, e.g.*, *Williams v. Smith & Nephew, Inc.*, 123 F. Supp. 3d 733, 742 (D. Md. 2015) (holding implied warranty claim is preempted because "the FDA, through the PMA process, expressly defines the scope of a device's 'intended use'") (citation omitted); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004) (implied warranty of merchantability claim preempted because it would "impose[] state requirements that relate to the safety and effectiveness of the" device); *Williams v. Bayer Corp.*, 541 S.W.3d 594, 604 (Mo. Ct. App. 2017) (implied warranty claim against PMA device "expressly preempted on its face as it directly contradicts the FDA's determination that [the device] is . . .

safe and effective"). Plaintiffs also cannot base claims on statements "blessed" by FDA for inclusion in the "FDA-approved BHR label." *Sedgwick* Mem. at 18.

Apart from such assertions, Plaintiffs subject to this motion have not identified any "warranties" Smith & Nephew allegedly made that induced them to obtain the device, and that were breached. *See, e.g.*, *Morris v. Biomet, Inc.*, 491 F. Supp. 3d 87, 108 (D. Md. 2020) (rejecting "[w]arranty by omission" because "an express warranty . . . requires an 'affirmative statement'") (citation omitted); *Fraser v. Wyeth, Inc.*, 857 F. Supp. 2d 244, 257-58 (D. Conn. 2012) ("manufacturer's representation in advertising or a warning label that a product is safe or effective, or an advertisement or warning label that does not adequately highlight a particular known or knowable risk does not create an express warranty in the absence of a guarantee that the particular product is free from all harmful side effects.").

Second, Plaintiffs' claims cannot be based on "information predat[ing] the FDA's PMA approval of the device" because such claims are preempted. *Sedgwick* Mem. at 18. Plaintiffs' experts offer several criticisms of Smith & Nephew's submissions to FDA prior to the PMA in May 2006, but under this Court's rulings such evidence is a "preempted attempt to undermine the FDA's PMA approval process." *Id*.; *Daubert* Ruling at *9-10; *see, e.g.,* David Dep. (Ex. BB) at 243-44 (contending that "information Smith & Nephew provided to the FDA in 2004, 2005, 2006 that led to the approval of the BHR device in the United States" was "not sufficient"); Truman (MDL) Report (Ex. V) at 21-22 (asserting evidence of "problems with resurfacing in sub populations" "prior to launch of the BHR in the USA," including article "cited in a PMA response to FDA questions during the FDA PMA review process"); *id*. 24 (similar).

Third, apart from Plaintiffs' preempted criticisms of the PMA process, Plaintiffs' experts have not identified alleged misrepresentations prior to October 2009. Although the Court has held

that misrepresentation claims can be based on the "omission" of material information, *Sedgwick* Mem. at 14-15, it has also stressed that it is not "imposing a duty on Smith & Nephew to seek out additional information and disclose it to surgeons," because any "duty to warn the medical community is preempted," *id*. at 20. Rather, any non-preempted misrepresentation claim "requires only that Smith & Nephew not create a misleading impression by failing to disclose other known information." *Id*. In other words, Plaintiffs must demonstrate that Smith & Nephew made a voluntary communication to doctors that "did not reflect Smith & Nephew's knowledge of the BHR . . . up until the point of surgery." *Id*. at 17.

Plaintiffs and their experts have not identified any such evidence of misrepresentations, particularly prior to October 2009. As the Court has recognized, Plaintiffs' core "theory of the case" is predicated on foreign "ad hoc" registry data, which they have argued "showed significantly worse success rates for the BHR in [1] women and [2] patients with smaller head sizes." *Redick* Mem. at 2. The Court previously has held that Plaintiffs' misrepresentation claims raise material factual disputes only where they are based on evidence that Smith & Nephew made affirmative "specific representations comparing its revision rates to those of its competitors," which, although accurate, could have been misleading by omission because "[f]or female patients and patients needing smaller head sizes, Smith & Nephew learned its revision rates were much worse" through the ad hoc registry reports. *Mosca* Mem. at 19.

As the Court has noted, Smith & Nephew "began to request and receive" these "ad hoc reports" from registries "in 2009." *Id.* 7. Specifically, Smith & Nephew received the first such ad hoc report on October 16, 2009. SN_BHR_MDL_0777009 (Ex. W); Ex. 14 to Plf. *Mosca's* Mem. in Support of Mot. for Summ. J. [D.E. 2514-16]. Plaintiffs' experts have recognized that Smith & Nephew did not have "ad hoc data specific to revision rates in women or patients with smaller

head sizes at any point in time in 2007 or 2008." Spears Dep. (Ex. EE) at 133-34; *see id.* at 134 ("certainly as I look at my report, I agree that it did not get into details like you're asking about for 2008 in terms of the revision rates for women and smaller head sizes"); Truman (MDL) Report (Ex. V) at 57 (showing no "sub-population rate" registry data prior to 2009); Shapiro (MDL) Report (Ex. T) at 23 ("in 2009, Smith & Nephew learned of higher-than-expected failure rates for women and patients with smaller head sizes through reports from the Australian registry"); David (MDL) Report (Ex. Z) at 18 ("Smith & Nephew knew since at least 2009 that the failure rates for women and smaller head sizes was significantly worse than the failure rate for the aggregate population and were higher than Smith & Nephew expected").

Thus, at least prior to October 2009, Plaintiffs do not have sufficient evidence to raise a genuine question of material fact as to their misrepresentation or warranty claims. Plaintiffs subject to this motion can be divided into three groups: (1) Plaintiffs who had BHR devices implanted between the approval of the device in May 2006 and September 2007 (*i.e.*, the date of the procedure in *Sedgwick*); (2) Plaintiffs who had BHR devices implanted between October 2007 and April 2009; and (3) Plaintiffs who had BHR devices implanted between May 2009 and September 2009. While the evidence varies somewhat between these three groups, it is insufficient for all Plaintiffs subject to this motion.

Plaintiffs with implant dates May 2006- September 2007: For Plaintiffs who had the BHR device implanted in September 2007 or earlier, the Court's analysis of the misrepresentation and warranty claims in *Sedgwick* is directly on point. *Sedgwick* involved a plaintiff who obtained the device in September 2007; the Court granted Smith & Nephew summary judgment on the ground that "there is no evidence Smith & Nephew had additional information that contradicted those assertions [regarding revision rates] before Mr. Sedgwick's surgery." *Sedgwick* Mem. at 18. In

particular, "Smith & Nephew did not begin to receive ad hoc reports from Australian and UK registries showing longer-term higher rates of revision for patients with smaller head sizes until 2009," and Plaintiffs therefore could not show that use of the overall revision rate was misleading for omitting these data. *Id*.; *Mosca* Mem. at 7-8 (discussing ad hoc reports received in October 2009 (Ad Hoc Report 425 and 408)). The Court further held that any "minimal evidence in the record that Smith & Nephew had reason to be aware that the overall revision rates it used to market the BHR . . . overstated the success of the product, particularly for smaller head sizes" was insufficient. *Sedgwick* Mem. at 19. The evidence could only "at best . . . support an inference that Smith & Nephew had a general awareness of the possibility it was overstating the success of the BHR," and did not demonstrate the required knowledge "that a representation is misleading or fails to include relevant information at the time it is made." *Id*. at 19-20. The Court's reasoning in *Sedgwick* is equally applicable to all the plaintiffs who had BHR devices implanted in September 2007 or earlier, and summary judgment should be granted on these same grounds. See Ex. A (identifying plaintiffs' BHR implant dates).

Plaintiffs with implant dates October 2007-April 2009: Further, Plaintiffs who had BHR devices implanted from October 2007 through April 2009 also lack evidence that raises a genuine issue of material fact. Plaintiffs' experts have contended that "Smith & Nephew executives knew about the revisions and causes of them for the BHR in late 2007" from public registry reports. Spears (MDL) Report (Ex. U) at 9. However, the experts have conceded that these 2007 data were reported "very early in the process," and "do[] not talk about specifically revision rates for women or smaller head sizes for BHR." Spears Dep. (Ex. EE) at 132-33. Nor have Plaintiffs identified any affirmative representations that Smith & Nephew made that were false or misleading in light of the public 2007 registry data. To the contrary, Plaintiffs' counsel has conceded that "there is

nothing misleading about th[e] Dear Doctor letter" Smith & Nephew sent in November 2007, concerning the Australian registry data, because "[t]his is still the state of what we, at least to this day, know that Smith & Nephew actually knew." Redick Trial Tr. (Aug. 12, 2021 a.m.) (Ex. FF) at 63.

The Court has noted that "[a]t least as of 2008, Smith & Nephew internal documents show a general awareness that peer-reviewed literature indicated that revision rates for the BHR were higher for females and patients with smaller head sizes than the overall revision rates for all patients." *Mosca* Mem. at 7. The Court cited internal correspondence from October 2008 that mentions "items recently" suggesting "BHR issues," including with "gender, [and] smaller head higher revision rates." Ex. 13 to Plf. *Mosca* Mot. for Summ. J. [D.E. 2514-15], at 3. However, as the Court held in *Sedgwick*, "a general awareness of the possibility it was overstating the success of the BHR" is insufficient to support a claim, absent evidence that Smith & Nephew knew "that a representation is misleading or fails to include relevant information at the time it is made." *Sedgwick* Mem. at 19-20. Plaintiffs also have failed to identify any representations that Smith & Nephew made to doctors in this time period that were false or misleading in light of the October 2008 "general awareness" of potential issues with "gender, [and] smaller head higher revision rates." *Id.* at 6; Ex. 13 to Plf. *Mosca* Mot. for Summ. J. [D.E. 2514-15], at 3.

Plaintiffs with implant dates May 2009–September 2009: Finally, there is also insufficient evidence to raise a genuine issue of material fact as to Plaintiffs who had BHR devices implanted from May 2009, through September 2009. Smith & Nephew sent a "Dear Doctor" letter in May 2009 about the risk of "pseudo-tumors." *See* Ex. 2 to Plf. *Mosca* Mot. for Summ. J. [D.E. 2514-4] at 9. However, Plaintiffs have not presented evidence that this letter was false or misleading in light of any information that Smith & Nephew had at the time. Indeed, the letter specifically noted

the potential that female patients were at higher risk, stating "the exclusive finding of 'pseudo-tumors' in female patients could be interpreted as a gender-specific higher susceptibility to metal ion hypersensitivity and stronger immune responses." *Id.* at 9. Plaintiffs' expert Mari Truman contends that "the rate of metal pathology" identified in the letter was "lower than the rate being identified in public registry data and especially lower than the rate in females identified in Ad Hoc report," but again, Smith & Nephew did not even receive the first ad hoc report until October 2009. Truman (MDL) Report (Ex. V) at 30. And Ms. Truman's report also acknowledges that ad hoc report 408 was received in mid-October 2009, but the Dear Doctor letter was mailed "months earlier." *Id*. at 31 ("These rates [in the ad hoc report] are much higher than the rates reported by S&N in the Dear Doctor letter mailed just months earlier").[9] Indeed, Plaintiffs' expert Ms. Truman states that the letter should be "commended" for its recommendations that doctors take additional precautions in light of the risk of pseudotumors. *Id*.[10]

Because there is no genuine dispute of material fact, summary judgment is appropriate as to the misrepresentation and breach of express warranty claims in connection with BHR implants prior to October 2009. *See, e.g., In re Mirena*, 982 F.3d at 125; *In re Lipitor,* 892 F.3d at 647-48.

[9] Ms. Truman criticizes Smith & Nephew because she "did not see a Dear Doctor letter correcting this statistic," Truman (MDL) Report (Ex. V) at 31, but the Court has ruled that Smith & Nephew had no obligation affirmatively to provide such information to physicians.

[10] To the extent Plaintiffs also assert claims relating to representations that "the use of as-cast metal instead of 'heat-treated' metal . . . produced a lower revision rate," *Sedgwick* Mem. at 16, such claims fail because "there is no evidence Smith & Nephew had additional information that contradicted those assertions" prior to October 2009, *id*. at 18. Indeed, this Court rejected such a claim in *Sedgwick* on these grounds, holding "it was not until 2015 that Smith & Nephew received data that undercut its assertions that the BHR's 'as-cast' metallurgy was responsible for a revision rate that was lower than its heat-treated competitors." *Id.*

B. Plaintiffs Cannot Support a Negligence Per Se Claim with Allegations That Smith & Nephew "Misbranded" the BHR.

For the same reasons, Plaintiffs cannot support a negligence per se claim based on allegations that Smith & Nephew made false or misleading statements regarding the BHR, such that the BHR was "misbranded" in violation of federal or state statutes. As the Court has noted, Plaintiffs "intend to offer essentially the same evidence underlying their negligent misrepresentation and breach of warranty claims to support" this misbranding theory of negligence per se. *See Redick* Mem. at 29, 31. For the reasons explained above, this theory cannot be supported with regard to Plaintiffs who obtained the BHR device prior to October 2009.

As the Court has held, Plaintiffs cannot base any "misbranding" theory on a purported "misrepresentation" in the FDA-approved labeling, because such a theory is preempted by federal law. *Id*. at 30 ("[A] claim that Smith & Nephew had a duty to change its labeling, or a claim challenging the adequacy of the FDA-approved labeling, is preempted" and cannot support a misbranding theory) (citing *In re BHR*, 300 F. Supp. 3d at 745). And even with regard to "non-FDA approved statements," *id*. at 29, Plaintiffs lack evidence that any misrepresentations were made prior to October 2009 for the reasons explained above. *See* § II.B*, supra*.

As a result, with regard to Plaintiffs who obtained devices prior to October 2009, Plaintiffs cannot support negligence per se with "misbranding" assertions, and summary judgment should be granted to Smith & Nephew.

III. SUMMARY JUDGMENT SHOULD BE GRANTED ON PLAINTIFFS' FAILURE TO TRAIN THEORY.

Plaintiffs also cannot support a negligence claim based on purportedly inadequate training provided by Smith & Nephew to Plaintiffs' implanting surgeons. "This court has already held that the PMA condition that required Smith & Nephew to implement a training program did not include requirements as to what the training must include and excluded as preempted testimony which

suggested Smith & Nephew had a duty to modify the training and testimony that the training should have informed surgeons of a 1,000-surgery learning curve." *Redick* Mem. at 29 (citing *Daubert* Ruling); *see also* Pls.' Response to Smith & Nephew's Motions to Exclude Expert Opinions (Jan. 6, 2021) [D.E. 2427] (Jan. 6, 2021) ("Pls' *Daubert* Resp.") at 86 ("FDA did not provide specific requirements for the content of the surgeon training program."). Thus, "[a] claim that Smith & Nephew had a duty to change its program would add to or differ from the requirement to merely implement the program and is preempted." *Redick* Mem. at 29 (citing *Daubert* Ruling at 15). And "[o]nce the FDA approved the training program, there appears to have been 'no requirement to make updates to that program.'" *Id*. (citing *Daubert* Ruling at 15).

Here too, Plaintiffs cannot assert that Smith & Nephew failed to "implement a training program," or "failed to provide the required training." *Id.* at 28. There is no evidence that the surgeon training violated any federal requirement. And the Court has held that "plaintiffs appear to have acknowledged that the training program was required to 'harmonize' with the device's labeling," *Id.* at 29, and Plaintiffs do not and cannot argue that the training provided did not meet that requirement. Plaintiffs' failure-to-train theory therefore fails for the same reasons the Court held in *Redick*. In addition, it is even more insufficient for the Plaintiffs subject to this motion, because Smith & Nephew did not even have the ad hoc data prior to October 2009. *See* pp. 9-10*, supra*. Because Plaintiffs cannot support a negligence claim based on any purported failure to train Plaintiffs' surgeons, summary judgment should be granted to Smith & Nephew.[11]

[11] In *Redick*, the Court held that "to the extent the plaintiffs claim that misleading revision rates were touted as part of the training program, such evidence may support a non-preempted negligent misrepresentation or breach of express warranty claim." *Redick* Mem. at 29. Here, however, the negligent misrepresentation claims fail for the reasons explained above. *See* § II.A*, supra*.

IV. SUMMARY JUDGMENT SHOULD BE GRANTED TO SMITH & NEPHEW ON PLAINTIFFS' PUNITIVE DAMAGES CLAIM.

In the MACC, Plaintiffs seek punitive damages based on the conclusory allegation that Smith & Nephew's "acts and omissions . . . constitute intentional, fraudulent, malicious and/or reckless conduct." MACC ¶ 605. Plaintiffs also have asserted that "Smith & Nephew Chose Profits Over Patient Safety" by marketing and selling the BHR in the United States as safe and effective. Pls.' *Daubert* Resp. [D.E. 2427] at 35-36. Plaintiffs do not and cannot meet the high standard necessary to support an award of punitive damages with respect to the BHR device for Plaintiffs who obtained their devices prior to October 2009.

First, as this Court has explained, "[a] claim for punitive damages is derivative and therefore survives if the plaintiffs' underlying claims that support it survive." *In re BHR*, 300 F. Supp. 3d at 736 n.3. Here, Plaintiffs cannot support their underlying claims for Plaintiffs who obtained their devices prior to October 2009. Accordingly, they cannot support punitive damages for this subpopulation of Plaintiffs.

Second, Plaintiffs cannot establish that Smith & Nephew engaged in "intentional, fraudulent, malicious and/or reckless conduct" with respect to Plaintiffs who were implanted with the BHR prior to October 2009. MACC ¶ 605. Smith & Nephew marketed and sold the BHR only after the FDA approved the device via the rigorous PMA process, based on a finding that it was safe and effective. Smith & Nephew was entitled to market the BHR as a safe medical device because "[t]hat is exactly what FDA approval means." *In re BHR*, 300 F. Supp. 3d at 745.

Further, any argument that punitive damages can be based upon a claim that Smith & Nephew "concealed ad hoc reports from the FDA," *Redick* Mem. at 35, must fail. This theory is inapplicable to Plaintiffs who obtained their devices prior to October 2009, because Smith & Nephew itself did not yet have any relevant ad hoc reports, and therefore could not "conceal" them.

See, e.g., pp.9-10, 16-17*, supra*. Further, as detailed above, there is no evidence that failure to report information to FDA was a cause of these Plaintiffs' alleged injuries in these cases. Under the Due Process Clause, a defendant's conduct that is "independent from the acts upon which liability was premised, may not serve as the basis for punitive damages." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003); *accord IGEN Int'l v. Roche Diagnostics GmbH*, 335 F.3d 303, 314 (4th Cir. 2003).

Likewise, after FDA approval, Smith & Nephew was entitled under federal law to continue marketing the BHR. *In re BHR,* 300 F. Supp. 3d. at 742 (holding that the FDA regulates the BHR system as a Class III device, has subjected it "to a rigorous approval process," and "continues" to regulate the BHR "even after receiving premarket approval"). Smith & Nephew submitted annual reports to FDA as required under its PMA approval, and, for each year relevant to these cases, FDA sent a letter back to Smith & Nephew verifying it was in compliance with PMA reporting requirements. Exs. C through P. Neither the sale nor the marketing of the BHR as "safe" can possibly support punitive damages in these cases.

In sum, Plaintiffs cannot support punitive damages in cases involving Plaintiffs with BHR implant surgery dates prior to October 2009.

CONCLUSION

For these reasons, summary judgment should be granted to Smith & Nephew as to the remaining claims of the Plaintiffs identified in Exhibit A, each of whom is a Plaintiff implanted with a BHR device prior to October 2009.

Dated: December 20, 2021

Respectfully Submitted,

/s/ Paul J. Zidlicky

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CERTIFICATE OF SERVICE

I, Paul J. Zidlicky, hereby certify that on this 20th day of December, 2021, I electronically filed the foregoing with the Court using the CM/ECF system, and thereby delivered the foregoing by electronic means to all counsel of record.

/s/ Paul J. Zidlicky
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